UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

SARA MARENTETTE, MATTHEW O'NEIL NIGHSWANDER, and ELLEN STEINLEIN, on behalf of themselves and all others similarly situated,	)	
Plaintiffs.	)	Case No. 1:15-cv-2837-PKC-RLM
v.	)	
ABBOTT LABORATORIES, INC.,	)	
Defendant.	)	

DEFENDANT'S MOTION TO DISMISS

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INTRODUCTION

Plaintiffs allege that Abbott's Similac Organic infant formula does not qualify as organic under the U.S. Department of Agriculture's ("USDA") regulations on organic foods. Their theory is that it contains ingredients those regulations ban. Plaintiffs' causes of action, asserted under state law, are all based entirely on the allegation that the product is not "organic" under federal law.

There is no dispute about whether the formula contains those ingredients. It does. They are listed on every package, and *every* ingredient challenged in this case is used in other organic infant formulas. USDA allows them to be used and knows they are used.

For several reasons, this case should be dismissed with prejudice. First, federal law preempts Plaintiffs' claims. Indeed, Plaintiffs are trying to do here exactly what the doctrine of preemption prevents: asserting state law causes of action that conflict with governing federal law. USDA, through an agent, has ***certified*** that Similac Organic is properly labeled as organic as a matter of federal law, which signifies that federal law allows all of its ingredients. The only federal appellate court to address the issue held that preemption bars plaintiffs using state law causes of action from arguing that a product with a federal organic certification is not organic. In addition, federal law holds state regulations of organic products invalid unless the Secretary of USDA approves them, but he has not approved any of the state statutes or causes of action that Plaintiffs assert here. For both of those two independent reasons, federal law preempts all of Plaintiffs' claims.

Second, federal law requires private parties who wish to challenge a federal organic certification to appeal to the Secretary of USDA, who has exclusive jurisdiction to hear the challenge and can maintain the congressionally mandated national uniformity of standards for organic foods. Plaintiffs failed to appeal to the Secretary, thereby failing to exhaust their administrative remedies, so their complaint must be dismissed.

Third, the complaint should be stayed or dismissed under the doctrine of primary jurisdiction because USDA is in the middle of formal rulemaking about the ingredients allowed

in organic infant formula. This is the paradigmatic case for deferring to an agency's expertise. This Court should not interfere with USDA's rulemaking by allowing this case to proceed.

Fourth, in a proposed rule and again in an interim rule, USDA stated that even *if* a final rule banning some ingredients is announced in the future, it will be accompanied by a two-year implementation period during which infant formula companies will have time to reformulate their formulas or relabel them. USDA recognizes that infant formula companies justifiably relied on the current version of the regulations, which allow all of the challenged ingredients to be used, and has expressly stated that those ingredients may be used in organic formula now and until the implementation period has run. Thus, if this Court is to rule on the merits of Plaintiffs' complaint today, it should be dismissed. Under current federal law, all of the challenged ingredients may still be used in organic infant formula. As explained below, only in October 2017—at the very earliest—might any of the challenged ingredients be banned. Plaintiffs' complaint should be dismissed.

Fifth, the complaint should be dismissed for defects in the state law causes of action. The label on Similac Organic is undeniably true, so Plaintiffs cannot state any cause of action, nor can they plead that by reasonably relying on the label they were misled about whether the formula contained the challenged ingredients—which again are listed on the label itself. In addition, the New York Court of Appeals has held that only injury the complaint alleges is not actionable, and the New York Plaintiffs also failed to provide the pre-suit notice that New York law requires. Again, the Court should dismiss the complaint with prejudice.

BACKGROUND

The First Amended Class Action Complaint admits that "federal regulations … control the labeling" of organic infant formula. (Compl., attached hereto as Ex. 1, ¶ 36.) Plaintiffs contend that Similac Organic is falsely labeled as organic, solely on the theory that it "contain[s] ingredients that federal law does not permit in organic foods." (*Id.* ¶¶ 1, 5, 25.)

The complaint alleges that Similac Organic contains "a spectacular array and substantial amount of ingredients prohibited in organic foods": "of the 49 ingredients in [Similac Organic],

more than half (26 ingredients) are not allowed in organic foods." (*Id*. ¶ 2.) The complaint, however, lists only 19 supposedly prohibited ingredients. (*Id.* ¶¶ 18, 27.) Plaintiffs assert that Similac Organic "is thus not 'organic' under federal law, and labeling it as such is misleading and deceptive under state law." (*Id*. ¶ 26.)

Pictures of Similac Organic are attached as an exhibit to the complaint. They show that the front of the product bears the "USDA ORGANIC" logo:

The back states the formula is "CERTIFIED ORGANIC BY QUALITY ASSURANCE INTERNATIONAL." The complaint admits that the label's list of ingredients includes all of the ingredients about which Plaintiffs now complain. (Compl. ¶ 35; *Id.* Ex. 1 at 3, 7, 10.)

As explained in detail below, federal law explicitly allows the challenged ingredients to be used in organic infant formula. The Secretary of USDA maintains what is known as the "National List" of approved synthetic ingredients for organic foods, and on that list is an entry for certain "nutrient vitamins and minerals." The challenged ingredients are all nutrient vitamins and minerals that may be used in organic foods. An alternative phrase for "nutrient vitamins and minerals" is "accessory nutrients." USDA regulatory documents often refer to "accessory nutrients" when discussing ingredients that are "nutrient vitamins and minerals," so this motion uses those terms interchangeably. Two of the accessory nutrients that are mentioned most often in the regulatory history are known as DHA and ARA. (Compl. ¶¶ 27(d), (e).)

The complaint suggests incorrectly that there is something unsafe about the challenged ingredients. For example, choline bitartrate is described as "[a] synthetic substance produced by the reaction of trimethylamine with ethylene oxide followed by treatment with tartaric acid. Trimethylamine and tartaric acid are both hazardous substances." (*Id.* ¶ 27(i).) Yet federal regulations recognize choline bitartrate as safe, or "GRAS," which means it can freely be used in

food. 21 C.F.R. § 182.8250(b).

Plaintiffs—one mother and one married couple—occupy just two paragraphs in the complaint. They are citizens of New York and California who allegedly bought Similac Organic at grocery stores and retail stores; and they thought it was organic. (Compl. ¶¶ 16-17.) They assert causes of action for breach of express warranty, violations of New York and California consumer fraud and false advertising laws, violation of the California Organic Products Act, and unjust enrichment. (*Id*. ¶¶ 68-137.)

ARGUMENT

A. Federal law preempts all of Plaintiffs' claims.

Plaintiffs' state law claims are premised on the idea that Similac Organic is falsely labeled as organic as a matter of federal law. But USDA has already determined that Similac Organic is properly labeled as organic as a matter of federal law, and Plaintiffs cannot use state law causes of action to reverse USDA's federal determination. In addition, the Act provides that state regulations of organic foods are invalid unless the Secretary of USDA approves them, but USDA has not approved Plaintiffs' state law claims as an appropriate regulation of whether Similac Organic is properly labeled as organic. For each those two independent reasons, federal law preempts all of Plaintiffs' claims.[1]

1. Federal law establishes uniform national standards for organic foods.

Congress enacted the Organic Foods Production Act (the "Act") in 1990 to "establish national standards governing the marketing" of organic foods and to "assure consumers that organically produced products meet a consistent standard." 7 U.S.C. § 6501. Before 1990, there were different organic standards under different states' laws. To fix this, the Act "contemplates a

[1] Counts 2-5 (consumer fraud and false advertising) are also subject to safe harbor provisions that provide a complete defense when the complained-of act is subject to and complies with federal law. N.Y. G.B.L. §§ 349(d), 350-d; *Porr v. Nynex*, 230 A.D.2d 564, 576 (N.Y. App. Div. 1997); *Am. Home Prods. v. Johnson & Johnson*, 672 F. Supp. 135, 144-45 (S.D.N.Y. 1987); *POM Wonderful v. Coca Cola*, 2013 WL 543361, at *5 (C.D. Cal.); *Ebner v. Fresh*, 2013 WL 9760035, at *4 (C.D. Cal.). Any claim that falls within the safe harbor, as counts 2-5 do, must be dismissed. *See, e.g., Alvarez v. Chevron*, 656 F.3d 925, 933-34 (9th Cir. 2011) (safe harbor applied to design defect claims because the design was *certified* pursuant to regulations).

certification program designed to effect national standards and to eliminate the preexisting 'havoc for the industry' caused by balkanized state regulations." *In re Aurora Dairy*, 621 F.3d 781, 793 (8th Cir. 2010) (quoting S. Rep. 101-357 (reprinted in 1990 U.S.C.C.A.N. 4656, 4943)). USDA enforces the Act; there is no private right of action. 7 U.S.C. § 6519.

2. Similac Organic is labeled as organic based on a federal certification.

Food may be sold as organic, under federal law, only if USDA's "certifying agents" "certify" that a handling operation which markets the food as organic "meets the requirements" of federal organic law. *Id.* § 6503(d). As their title indicates, certifying *agents* act on behalf of USDA and its National Organic Program. *Id.* §§ 6503(a), (d). They "serve in a quasi-governmental function," and their organic certifications "transmit[] a government message" that the federal organic standards are met. *Mass. Indep. Certification v. Johanns*, 486 F. Supp. 2d 105, 119, 121 (D. Mass. 2007); *see also Harvey v. Veneman*, 396 F.3d 28, 37 (1st Cir. 2005) (certification is "USDA certification," not "private certification").

Prospective certifying agents must apply to USDA, and they are subject to audit by USDA. In order to become an accredited certifying agent, an organization must prove to USDA's satisfaction "its ability to fully comply with and implement the [federal] organic certification program." 7 C.F.R. § 205.504; *see also id.* § 205.501(a)(1).

Only after a certifying agent certifies that a food operation complies with the federal organic standards for product composition and labeling may its package bear the "USDA ORGANIC" logo. *Id.* §§ 205.301(b), 205.303(a)(4)-(5), 205.311. Certifiers subject food producers to a rigorous process. *Id.* §§ 205.403(a)(1), (a)(2), (c)(1), (d). Of key importance here, the certifying agent must "***review all multi-ingredient products*** before they are sold" in order to "***verif[y] that all … ingredients … comply with the regulations***" while considering "any restrictions on substances as indicated on the National List…"[2] (As explained below, USDA's National List is a list of synthetic ingredients that the Secretary has approved for use in organic

[2] Ex. 2, USDA, *National Organic Program Handbook*, http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5087109 (emphasis added).

foods.) If the certifying agent determines that "all procedures and activities of the applicant's operation are in compliance" with federal organic regulations, certification is granted. *Id*. § 205.404(a). Certification is a federal determination that its recipient "is in compliance with the Act" and its regulations. 7 C.F.R. § 205.2.

The certifying agent for Similac Organic is Quality Assurance International, which has been accredited by USDA and therefore acts on USDA's behalf. (A list of all USDA-accredited certifying agents can be found at http://www.ams.usda.gov/sites/default/files/media/Organic CertifyingAgents.pdf.) Each container of Similac Organic states that it is "CERTIFIED ORGANIC BY QUALITY ASSURANCE INTERNATIONAL."

3. Plaintiffs cannot use state law claims to overturn the certification that Similac Organic is, as a matter of federal law, organic.

"When Congress enacted the [Act], one of its objectives was to replace the patchwork of existing state regulations with a national standard defining organic food. State law that poses an obstacle to the establishment of the national standard should therefore be preempted." *In re Aurora Dairy*, 621 F.3d at 794. This is commonly known as conflict preemption.

Plaintiffs assert Similac Organic is falsely labeled as organic, on the theory it contains ingredients that federal law bans from organic foods. But USDA's certifying agent has already certified that Similac Advance is properly labeled as organic as a matter of federal law. That certification cannot be challenged under state law, or else the uniform national standards Congress enacted would be "subject to challenge under the statutes and common laws of all fifty states." *Id.* at 794. There is plainly a conflict between a federal law authorizing a producer to label its formula as organic and state law causes of action that would impose liability for that very label.

The Eighth Circuit has addressed this exact issue. The plaintiffs there claimed the defendants "sold milk as organic when in fact it was not organic." *Id*. at 796. In other words, just like Plaintiffs here, they were claiming "violations of state law arising from [the producer's] alleged failure to comply" with the Act and its regulations. *Id*. at 787-88.

The Court of Appeals rejected plaintiffs' theory, holding that under federal law, the organic certification (by Quality Assurance International, in fact) was dispositive and not challengeable by private plaintiffs: "compliance with the [organic] regulations is not a separate requirement independently enforceable via state law." *Id*. at 796. Allowing plaintiffs to challenge a federal organic certification under state law would lead to "numerous court systems adopt[ing] possibly conflicting interpretations of the same" organic regulations, and to "an increase in the 'consumer confusion' ... that characterized the period before the [Act]." *Id.* (quoting S. Rep. 101-357, 1990 U.S.C.C.A.N. 4656, 4943).[3]

For those reasons, "any attempt to hold [a defendant] liable under state law based upon its products supposedly not being organic directly conflicts with the role of the certifying agent." *Id*. at 797. State law claims therefore cannot be used to "set aside" an organic certification or to attack the food "being labeled as organic in accordance with the certification." *Id*.; *see also Quesada v. Herb Thyme Farms*, 166 Cal. Rptr. 3d 346, 355 (Ct. App. 2013) (holding preempted all claims requiring "proof of facts that, if found by the certification agent, would have precluded [federal] certification"), *review granted*, 323 P.3d 1 (Cal. 2014).[4] That is exactly what Plaintiffs seek to do here. Their claims are all preempted and must be dismissed.

This result is not unique to the organic realm. For example, under the Federal Meat Inspection Act and the Poultry Products Inspection Act, USDA reviews and preapproves labels of meat products. Courts refuse to allow lawsuits alleging that those labels are misleading:

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[3] "It is easy to see why Congress would not want to allow states to impose disclosure requirements of their own on packaged food products, most of which are sold nationwide. Manufacturers might have to print 50 different labels, driving consumers … crazy." *Turek v. Gen. Mills*, 662 F.3d 423, 426 (7th Cir. 2011).

[4] In their letter to this Court opposing Abbott's request to file a motion to dismiss, Plaintiffs relied exclusively on *Segedie v. Hain Celestial Group*, 2015 WL 2168374 (S.D.N.Y.), which disregarded *Aurora Dairy* for several erroneous reasons. For example, *Segedie* said the fact that there are many certifying agents shows Congress expected divergent interpretations of organic regulations. *Id*. at *6. *Segedie* also said that Congress provided no federal remedy "for consumers duped into purchasing falsely labeled organic products." *Id.* at *7. Both points are wrong, and for the same reason: as discussed below, the Act allows (in fact, requires) dissatisfied consumers to appeal a product's organic certification to the Secretary of USDA, who maintains national uniformity in interpreting the organic regulations.

"allowing a jury to weigh in on preapproved USDA labels would surely conflict with the federal regulatory scheme … Plaintiffs concede that the [products] are stamped with the USDA's approval … If a jury came to the same conclusion as the USDA, it would be a waste of effort; if a jury instead came to a different conclusion…, the jury verdict would improperly 'trump' the USDA's authority." *Trazo v. Nestle USA*, 2013 WL 4083218, at *9 (N.D. Cal.); *see also Kuenzig v. Kraft Foods*, 2011 WL 4031141, at *7 (M.D. Fla.) (same, citing cases). "Receiving pre-approval of labels must be given preemptive effect." *Barnes v. Campbell Soup*, 2013 WL 5530017, at *5 (N.D. Cal.) (same).[5] That principle dooms all of Plaintiffs' claims here.

4. Abbott is certified to use the term "organic" on Similac Organic labels as a matter of federal law.

At the pre-motion conference, Plaintiffs argued that even if state law challenges to the USDA ORGANIC logo are preempted, because the word "organic" appears on the Similac Organic label apart from the logo, it can still be challenged. That is incorrect.

When the maker of a product like Similac Organic is certified as organic under federal law, it is entitled to use ***both*** the USDA ORGANIC logo and the word "organic." *See, e.g., Mass. Indep. Certification v. Johanns*, 486 F. Supp. 2d 105, 109 (D. Mass. 2007) (only certified organic food producers may "label their products as 'organic'").[6] State law challenges to Similac Organic's use of the word "organic" are therefore preempted. *Aurora Dairy*, 621 F.3d at 797 (state law claims cannot be used to attack food that is "labeled as organic in accordance with the [federal organic] certification"). The two are inseparable. Under the Act, "organic" is a "labeling term that refers to an agricultural product produced in accordance with" the Act and its regulations, 7 C.F.R. § 205.2; *see also id.* §§ 205.102, 205.300(a); 7 U.S.C. § 6505, just as the

[5] As a second example, another line of cases holds preempted state law causes of action challenging FDA-preapproved representations about medical devices. *See, e.g., Horowitz v. Stryker*, 613 F. Supp. 2d 271, 285-288 (E.D.N.Y. 2009); *Desabio v. Howmedica Osteonics*, 817 F. Supp. 2d 197, 206 (W.D.N.Y. 2011).

[6] *See also* Ex. 3, USDA, *Organic Labeling*, http://www.ams.usda.gov/rules-regulations/organic/labeling ("If you are not certified you must not make any organic claim … or use the USDA organic seal anywhere on the package."); Ex. 4, USDA, *Enforcement Activity*, http://www.ams.usda.gov/services/enforcement ("USDA organic regulations describe the specific standards that … processors must meet to use the word 'organic' or the USDA organic seal").

USDA ORGANIC logo may only be used for products meeting those requirements, 7 C.F.R. § 205.311(a). Accordingly, "[o]nly products meeting these requirements may be labeled as 'organic' ***and*** bear the USDA organic seal." *Partlo v. Johanns*, 2006 WL 1663380, at *8 (D.D.C.) (emphasis added), *aff'd* 224 F. App'x 7 (D.C. Cir. 2007).

5. Federal law preempts Plaintiffs' causes of action because the Secretary has not approved them.

States that wish to regulate the labeling of foods as organic may do so only with the USDA Secretary's approval, 7 U.S.C. § 6507(b)(1), (2); 7 C.F.R. § 205.620(e), to ensure the proposed state regulations "are consistent with the goals" of the Act, Ex. 5, S. Rep. 101-357, 1990 WL 258976, at *4949 (1990). The Act and its regulations thereby expressly "do preempt State statutes and regulations related to organic agriculture." Ex. 36, 65 Fed. Reg. at 80,682.

Plaintiffs' state tort and statutory claims have never been approved by USDA to regulate whether a product can properly be labeled as "organic." New York has never even applied to have a state organic program. California does have a state organic program that the Secretary approved, but California did not seek and was not granted permission to allow private plaintiffs to use existing California statutes or causes of action to enforce the Act (*see* California Organic Products Act, Cal. Health & Safety Code §§ 110810 *et seq*.). Thus, as the California Court of Appeal has held, private parties may not enforce it. *Quesada*, 166 Cal. Rptr. 3d at 357-58 (private enforcement of COPA through injunctive relief would be inconsistent with the National Organic Program and other provisions of COPA and is not permitted).

The only enforcement mechanism in California's organic program is fines and penalties levied by the state itself, Cal. Health & Safety Code § 110915[7]—the same enforcement federal law provides, 7 U.S.C. 6519. In California's program, citizens are *not* authorized to sue in court to contest a decision such as an organic certification that they believe to be erroneous. Cal. Food & Agr. Code § 46016.5; 3 Cal. Code Reg. §§ 1391.1, .3, .5; 7 C.F.R. § 205.668. The same holds

[7] *See also* Ex. 6, USDA, *State Organic Programs Compliance and Enforcement*, http://www.ams.usda.gov/services/enforcement/organic/state-compliance (describing enforcement by the state itself, not by private litigants).

true under federal law. Under the Act, "citizens have no authority … to investigate complaints alleging violation of the Act or [its] regulations." Ex. 36, at 80,627. Therefore, Plaintiffs' attempt to act as private enforcer of federal or state organic product regulations fails.[8]

B. The complaint must be dismissed for lack of subject matter jurisdiction, because Plaintiffs failed to exhaust administrative remedies.

Rather than allow consumers to assert state law claims in court, inevitably interfering with uniform federal standards, the Act provides them with a single recourse if they disagree with an organic certification. "Persons" who contend that a certifying agent's action "is inconsistent with the organic certification program" may take an expedited appeal of the agent's decision to the Secretary of USDA, and only after that appeal may the plaintiff proceed to District Court to challenge the Secretary's final decision. 7 U.S.C. §§ 6520(a)(2), (b); *see also id.* § 6502(15) ("the term 'person' means an individual"). This process is designed to ensure that uniform national standards are maintained.

Plaintiffs cannot substitute a civil lawsuit in this Court for the required appeal to the Secretary. In *All One God Faith v. Hain Celestial Group*, 2009 WL 4907433 (N.D. Cal.), for example, the plaintiff alleged, just as Plaintiffs here allege, that the defendants were "using the term 'organic' when [their] products are not in fact 'organic' as that term is defined" in federal regulations. *Id*. at *1. The court dismissed their lawsuit.

The court first explained that USDA "accepts all consumer … complaints regarding alleged misuse of the word 'organic,'" and USDA "has rejected private enforcement actions" because "'[c]itizens have no authority under the [regulations] to investigate complaints alleging violation of the Act or these regulations," *id*. at *3 (quoting 65 Fed. Reg. 80,548, 80,627). "The [National Organic Program] is ultimately responsible for the oversight and enforcement of the program, ***including … cases of fraudulent or misleading labeling***." *All One God Faith v. Hain Celestial Group*, 2011 WL 4433817, at *3 (N.D. Cal.) (emphasis added). The Act "provides

[8] The sole case about preemption on which Plaintiffs relied in opposing Abbott's request for permission to file a motion to dismiss, *Segedie*, 2015 WL 2168374, did not address the lack of approval by the Secretary of any private enforcement of organic laws.

specifically that a district court has subject-matter jurisdiction only upon the appeal of a final decision of the Secretary of the USDA," *All One God Faith*, 2009 WL 4907433, at *6 (citing 7 U.S.C. § 6520(b)), so the lawsuit had to be dismissed. Here, because Plaintiffs never appealed to the Secretary, they have not asserted any claims over which this Court has jurisdiction.

The case on which Plaintiffs rely, *Segedie*, 2015 WL 2168374, did not address the requirement that plaintiffs must exhaust their administrative remedies. To the contrary, *Segedie* illustrates the drawbacks of permitting private plaintiffs to pursue state claims rather than their administrative remedies. *Segedie* held that USDA's organic regulations ban ingredients such as DHA and ARA from organic infant formulas, *id*. at *9, but, as explained below, USDA itself has said that DHA and ARA are proper ingredients in organic infant formulas today and will remain so for at least two more years. Those opposing views of what USDA's own regulations say puts formula makers such as Abbott in an untenable position, with a court and the responsible agency disagreeing about whether universally used ingredients are banned.

C. This Court should defer to USDA's primary jurisdiction.

In asserting that USDA bans the challenged ingredients, the complaint omits a key fact: USDA is now engaged in formal rulemaking to create new rules for allowable ingredients in organic infant formula. That process is not done—USDA has not yet published a final rule—and this Court should reject Plaintiffs' attempt to jump the gun. "Under the primary jurisdiction doctrine, it would be inappropriate for this Court to assume the USDA's regulatory role, interpret the [National Organic Program's] regulatory framework, and impose standards that the USDA itself has refused to impose" on organic producers. *All One God Faith v. Hain Celestial*, 2009 WL 4907433, at *7 (N.D. Cal.). Plaintiffs' claims should be stayed or dismissed.

1. Federal law allows approved synthetic ingredients in organic foods.

Food may bear the "USDA ORGANIC" logo or the word "organic" on its label if it is, by weight, at least 95 percent organically produced; the remaining ingredients may be "nonorganically produced agricultural products produced consistent with the National List." 7 C.F.R. § 205.301; *see also* 7 U.S.C. § 6505. The Act directed the Secretary to create the National

List, which identifies synthetic and other non-organic ingredients that may be used in organic foods. 7 U.S.C. § 6517(a). The Secretary's list is at 7 C.F.R. § 205.605(b).

The entry on the National List at issue in this case allows organic foods to include synthetic "[n]utrient vitamins and minerals, in accordance with 21 C.F.R. § 104.20, Nutritional Quality Guidelines For Foods." 7 C.F.R. § 205.605(b). This entry has been present ever since USDA first promulgated the National List in 2000. Ex. 36, at 80,658. It took effect in October 2002, when the National Organic Program was fully implemented.

The regulation it mentions, section 104.20, identifies recommended amounts of various nutrients, such as vitamin A, vitamin C, vitamin B12, and biotin. 21 C.F.R. § 104.20(d). Each of those is provided by ingredients that Plaintiffs challenge.

The regulation also states that "nutrient(s) may appropriately be added to a food that replaces traditional food in the diet to avoid nutritional inferiority…" *Id.* § 104.20(e).[9] Infant formula, of course, replaces breast milk in the diet of infants, which creates a need for supplementation. In order to avoid nutritional inferiority, the challenged ingredients replace compounds found in breast milk. To take a few examples, "[a]ll of the vitamins, except K, are found in human milk in nutritionally significant concentrations." R. Jenness, *The composition of human milk*, available at http://www.ncbi.nlm.nih.gov/pubmed/392766. Many of the challenged ingredients are synthetic preparations of vitamins: ascorbyl palmitate (vitamin C), beta-carotene (vitamin A), cyanocobalamin (vitamin B12), cholecalciferol (vitamin D3), lutein (vitamin A), calcium pantothenate (vitamin B), and biotin (vitamin B). Sodium selenate provides selenium, which is found in breast milk. (Ex. 23 at 4.) Nucleotides "are also found in human breast milk." (Ex. 27 at 3.) "[B]reast milk and ARA/DHA supplemented formulas are good sources" of DHA and ARA. (Ex. 9 at 9.) Choline, inositol, carnitine, and taurine are all present in breast milk.[10]

[9] The case on which Plaintiffs rely stated that the defendant's argument "hinges on the interpretation" of § 104.20(f). *Segedie*, 2015 WL 2168374, at *8. The court in *Segedie* did not even consider § 104.20(d) or (e); in fact *Segedie* contained ***no*** analysis particular to organic infant formula, perhaps because the plaintiffs in *Segedie* also challenged 71 other organic products.

[10] Y.O. Ilcol et al., *Choline status in … breast milk*, available at http://www.ncbi.nlm.nih.gov/

Finally, section 104.20 states that "[n]utrient(s) may be added to foods as permitted or required by applicable regulations established elsewhere in this chapter." *Id*. § 104(f). "This chapter" is Chapter I of 21 C.F.R. One part of that chapter (Part 182, Subpart I) allows nutrients that are generally recognized as safe ("GRAS") to be added to food. As one example, biotin—one of the ingredients Plaintiffs challenge (Compl. ¶ 27(p))—is GRAS and may be added to food. 21 C.F.R. §§ 182.8159. In fact, nearly every ingredient Plaintiffs challenge "is generally recognized as safe (GRAS) for use in food and provides an essential nutrient." (Ex. 7, Technical Evaluation Report on Nutrient Vitamins and Minerals for the National Organic Standards Board, at 13; *see also id.* at 33-36, 37.) Another part of Chapter I (Part 107) is the Infant Formula Act regulations, which ***require*** biotin to be added to all infant formulas and the amount disclosed, 21 C.F.R. §§ 107.10(a)(2) & (b)(2), 107.100(a); *see also* 21 U.S.C. § 350a(i).[11] The Court will note that Appendix A shows that biotin is added to *every* organic infant formula.

Continuing the biotin example, there is no possible argument that the biotin added to organic infant formula must be organic; biotin is one of the many accessory nutrients that is "only or mainly produced chemically." (Ex. 7, Technical Evaluation Report, at 21; *see also id.* at 26, 41.) The point of biotin being included in the group of ingredients to which 21 C.F.R. § 104.20 refers is that it qualifies under the "nutrient vitamin and mineral" exception on the National List, which means it may be added to organic foods in synthetic form.

In other words, Plaintiffs are asking this Court to *bar* Abbott from adding to Similac Organic an ingredient that federal law *requires*. And biotin is not, of course, the only example. Many of the other challenged ingredients are required by the Infant Formula Act.

The National List entry for synthetic "nutrient vitamins and minerals" is often referred to as allowing "accessory nutrients" to be added to organic foods, because "accessory nutrients"

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pubmed/16043031 (choline compounds in breast milk); M. Jóźwik et al., *Human breast milk sugars and polyols over the first 10 puerperium days*, available at http://www.ncbi.nlm.nih.gov/pubmed/23349109 (inositol levels in breast milk); A. Sandor et al., *On carnitine content of the human breast milk*, available at http://www.ncbi.nlm.nih.gov/pubmed/7058085 (carnitine levels).

[11] Even though it purported to address § 104.20(f), *Segedie* did not consider the GRAS regulations or the Infant Formula Act regulations.

was the term the National Organic Standards Board (the "Board"), a 15-member group established by the Act to assist the Secretary in developing organic standards, 7 U.S.C. § 6518, used when proposing it. (Ex. 8, National Organic Standards Board, Final Recommendation Addendum Number 13, The Use of Nutrient Supplementation in Organic Foods, at 1.) The Board described accessory nutrients as "useful to promote optimal health" and cautioned that excluding them from organic foods would result in "limiting ourselves given future nutritional discoveries." (*Id.*) Among the examples the Board itself gave of beneficial accessory nutrients were inositol, choline, carnitine, and taurine. (*Id.*) All four are ingredients in Similac Organic today. Plaintiffs claim that federal law ban all four. (Compl ¶¶ 27(c), (h), (i), (k), (n).)

2. USDA *rejects* challenges to the addition of accessory nutrients to Similac Organic and other organic infant formulas.

After "nutrient vitamins and minerals" were added to the National List, a complaint was filed with USDA, challenging the use of DHA and ARA in organic infant formula. (Ex. 9, Letter from NOP to USDA Office of Compliance and Analysis (Nov. 3, 2006), at 1.) The National Organic Program analyzed those nutrients, as well as nucleotides and taurine. (*Id.*) After noting that the exception for "nutrient vitamins and minerals" originated with the Board's accessory nutrient recommendation, the National Organic Program determined that DHA, ARA, nucleotides, and taurine are all "acceptable ingredients for organic infant formulations." (*Id.* at 1-2.) Again, all four of those ingredients are in Similac Advance Organic today. And again, Plaintiffs challenge all four. (Compl ¶¶ 27(b), (c), (d), (e).)

In April 2008, a new complaint was filed with the National Organic Program by The Cornucopia Institute, an advocacy group. (Ex. 10, Cornucopia Institute Complaint (Apr. 14, 2008).) Cornucopia complained about the use of DHA and ARA in organic foods, including ***Similac Organic*** in particular. (*Id.* at 1.) Cornucopia argued those ingredients are banned from organic foods because they are not on the National List. (*Id.* at 1.) This complaint, too, failed.

As a result of the accessory nutrient entry that USDA placed on the National List in 2000, and USDA's application of it since then, numerous accessory nutrients are found today in all

organic infant formulas.[12] USDA acknowledges their widespread use. In January 2012, USDA explained that "essentially all organic infant formula" contains DHA and ARA. (Ex. 11, Proposed Rule, National Organic Program Sunset Review (2012) for Nutrient Vitamins and Minerals, 77 Fed. Reg. 1980, 1990.) Those are, of course, ingredients that Plaintiffs challenge.

3. USDA begins formal rulemaking regarding the use of accessory nutrients in organic infant formulas.

The Act includes a sunset provision, pursuant to which each entry on the National List expires every five years unless renewed by the Secretary. 7 U.S.C. § 6517(e). As explained above, the "nutrient vitamins and minerals" entry took effect in October 2002. In October 2007, the Secretary renewed it, so it was scheduled to expire five years later, in October 2012.

In March 2010, as part of its regular five-year review of the National List for 2012, the National Organic Program published an Advance Notice of Proposed Rulemaking to announce the upcoming sunset of ingredients on the National List. (Ex. 12, National Organic Program, Sunset Review (2012), 75 Fed. Reg. 14500) The exemption for "nutrient vitamins and minerals," along with many other exemptions, would expire in October 2012 if not renewed. (*Id*. at 14500.)

In April 2010, the National Organic Program announced a proposed new approach to accessory nutrients. (Ex. 13, National Organic Program Monthly Report.) The National Organic Program first recounted its decision in 2006 to allow DHA, ARA, and other synthetic ingredients to be added to organic infant formula as accessory nutrients. (*Id.* at 2.) It then explained that after consulting FDA about food supplementation policy, the National Organic Program would begin formal rulemaking to amend the "nutrient vitamins and minerals" exception, to establish which accessory nutrients could be used in the future in organic infant formula. (*Id*.) The National Organic Program also planned on "provid[ing] a transition time for businesses to reformulate products to comply with the [new] regulations" once those regulations were issued. (*Id*.)

Miles McEvoy, then (and still) the head of the National Organic Program, asked the

[12] The chart at Appendix A shows the use in organic infant formulas of all of the ingredients that Plaintiffs challenge. None of those ingredients are unique to Similac Organic; most are used in ***all*** organic infant formulas.

Board to "reevaluate its recommendation for nutrient vitamins and minerals during the 2012 sunset process and provide specific recommendations regarding the scope of permitted vitamins, mineral and nutrients in organic food products." (Ex. 14, Action Memorandum for the Chairman of the Board, at 3.) Mr. McEvoy acknowledged that "many certifiers and certified operations have made decisions" based on existing regulations. (*Id*.) He repeated that there will be "plenty of time for businesses to make the changes" after the final regulations are issued. (Ex. 15, Apr. 26, 2010 Tr., at 116.) There would be "ample time for that transition to occur" after the "proposed final rulemaking process" was done." (Ex. 16, Apr. 27, 2010 Tr., at 61.)

In 2011, Mr. McEvoy rejected another complaint filed by The Cornucopia Institute. (Letter, attached hereto as Ex. 17, at 1.) Cornucopia complained that Dean Foods sold milk that contained DHA even though "DHA is not on the National List." (*Id.*) After again recounting the history, Mr. McEvoy stated that "***[u]ntil the [National Organic Program] publishes final [rules]***, ***DHA remains allowed for use in new and existing certified organic products***." (*Id.* at 2 (emphasis added).) Plaintiffs' complaint flies in the face of that statement.

In January 2012, USDA published a proposed rule for public comment. (Ex. 11.) It would amend the National List to include an entry for "Vitamins and minerals … For infant formula—vitamins and minerals as required by 21 C.F.R § 107.100 or § 107.10." (*Id.* at 1983.) Those are the Infant Formula Act regulations. "[T]he vitamins and minerals required by FDA for infant formula, would be permitted for addition to organic infant formula." (*Id.* at 1985.)

The proposed rule recounted the history, and it explained that "[m]ost of the organic infant formulas in the current marketplace contain some added ingredients which are permitted, but not required by FDA, such as ARA, DHA, nucleotides, taurine, carnitine, [and] lutein." (*Id.* at 1984.) (Plaintiffs challenge all of those ingredients.) The proposed rule explained that those ingredients would not be covered by the proposed "Vitamins and minerals" entry on the National List, so, *if the proposed rule later went into effect as a final rule*, they would be banned from organic foods *unless* they were added separately to the National List. (*Id.* at 1984-85.)

Some of the challenged ingredients were later petitioned for separate addition to the

National List. The Board denied some of the petitions—for ascorbyl palmitate, beta-carotene, L-carnitine, lutein, nucleotides, and taurine—in October 2012. For other challenged ingredients—ARA, DHA, choline chloride, choline bitartrate, and M-inositol—the Board ***approved*** the petitions, so USDA may now add them to the National List by formal rulemaking. 7 U.S.C. § 6517(d). (The status of petitions for additions to the National List is at USDA, *Petitioned Substances*, http://www.ams.usda.gov/rules-regulations/organic/national-list/petitioned.)

The Board's denial of some of those petitions did ***not***, however, remove the "nutrient vitamins or minerals" exception or any part of it from the National List. In connection with a sunset review, which is how the "nutrient vitamins or minerals" exception is being reviewed, "the [Board] may recommend … removal from the National List. If USDA accepts the [Board's] recommendation, then USDA may initiate rulemaking to remove the substance from the National List. This process includes an additional opportunity for public comments." (Ex. 18, USDA, *Sunset Review Process*, http://www.ams.usda.gov/rules-regulations/organic/nosb/sunset-review.) Rulemaking on the "nutrient vitamins and minerals" exception is, as explained below, still underway, and USDA has extended the sunset date of that exception to ***October 2017***, so the exception will remain in place until then, with ***all*** accessory nutrients allowed in infant formula, unless in the meantime USDA amends or repeals that exception via a final rule.

The proposed rule was extremely clear that organic infant formula companies needed to take no immediate action. "Prohibitions on the use of ingredients affected by this action would not be enforced until the compliance date." (*Id.* at 1980.) The National Organic Program announced its intention to "provide sufficient time for the organic trade to adjust product formulations … or to consider relabeling products." (*Id.* at 1981.) Accordingly, USDA "proposes a two year implementation phase before this rule becomes effective." (*Id.* at 1990.)

In September 2012, prior to the scheduled sunset in October of the "nutrient vitamins and minerals" exemption, USDA issued an interim rule. (Ex. 19, National Organic Program; Sunset Review (2012) for Nutrient Vitamins and Minerals, 77 Fed. Reg. 59,287.) The interim rule stated that USDA is still working on a final rule, but for now "this interim rule ***continues the allowance***

for nutrient vitamins and minerals" found on today's the National List, which "***enables the industry to continue with the status quo until additional public comments are received and a final rule is published.***" (*Id.* at 59,289.) Once again, the interim rule explained that a "two year compliance date" was proposed for after the final rule. (*Id.* at 59,288.)

USDA has not yet issued a final rule. The current version of the National List, which continues to allow synthetic accessory nutrients to be added to organic infant formula, remains in place. The effect of the interim rule was to extend the "nutrient vitamins and minerals" sunset date to ***October 21, 2017*** (Ex. 20, USDA, *National List Sunset Dates*, http://www.ams.usda.gov/sites/default/files/media/NOP-SunsetDates.pdf, (Nov. 13, 2014), p. 14 of 18), so accessory nutrients will be allowed in organic infant formula until then or until USDA issues a final rule. *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (for an agency action to be final, the action must (1) "mark the 'consummation' of the agency's decision making process" and (2) "be one by which 'rights or obligations have been determined,' or from which legal consequences will flow."); *see also* Ex. 21, Motion to Dismiss, *Center for Food Safety v. Vilsack*, No. 15-cv-1590, Dkt. 16, at 15, 16 (N.D. Cal. July 17, 2015) (Secretary of USDA: a Sunset Notice is not "final agency action" and "is far from the 'consummation' of USDA's decision making process.").

4. This Court should defer to USDA's primary jurisdiction and allow USDA to finish its rulemaking.

USDA has not finished its rulemaking, and the content of the forthcoming final rule is not known. Nor is it known how many years USDA will grant the makers of organic infant formula to comply with the new regulation, assuming the new regulation amends the National List.

The doctrine of primary jurisdiction was designed for this situation, to prevent a court from commandeering an agency's ongoing work. It would "usurp" an agency's expertise to hear a case when the agency is "currently engaged in rulemaking procedures to *change* its existing requirements." *Ivie v. Kraft Foods*, 2013 WL 685372, at *7 (N.D. Cal.); *see also Backus v. General Mills*, 2015 WL 4932687, at *18-19 (N.D. Cal.) (primary jurisdiction because FDA rulemaking was underway and FDA set a compliance date of 2018). When a matter "currently is

under the [National Organic Program's] review, … it would be inappropriate for this Court to adjudicate Plaintiff's … claim[s] and impose a potentially conflicting set of standards." *All One God Faith v. Hain Celestial Group*, 2010 WL 2133209, at *7 (N.D. Cal.).[13]

The Second Circuit uses four factors to evaluate whether a court should defer to an agency's primary jurisdiction. All four favor deferring here. The first is whether the question is within the conventional expertise of judges or whether it involves technical or policy considerations within the agency's expertise. *Ellis v. Tribune Television*, 443 F.3d 71, 82-83 (2d Cir. 2006). The proper ingredients for organic infant formula are plainly within USDA's expertise. Judges have no expertise in determining, for example, whether DHA or ARA ought to be allowed, or whether an organic infant formula containing them should be labeled as organic. The Act delegates to the Secretary, not to any court, responsibility for promulgating the National List of approved synthetic ingredients and for hearing appeals of organic certifications.

The second factor is whether the matter at issue is within the agency's discretion. *Id.* at 83. It is. Again, the Act gave the Secretary discretion to decide what entries to make on the National List. 7 U.S.C. § 6517(a). The "labeling and marketing of 'organic' products falls within the exclusive jurisdiction of the USDA." *All One God Faith*, 2009 WL 4907433, at *8.

The third factor is whether there is a substantial danger of inconsistent rulings. *Ellis*, 443 F.3d at 83. That risk has already materialized. The court in *Segedie* acknowledged that its ruling would enable different district courts to reach different decisions about the proper ingredients for organic infant formula. *Segedie*, 2015 WL 2168374, at *6. Eliminating those differences was the primary reason Congress passed the Act in the first place, and it was the reason the Act requires

[13] *See also Town of Riverhead v. CSC Acquisition-NY*, 618 F. Supp. 2d 256, 270 (E.D.N.Y. 2009) (primary jurisdiction doctrine to avoid danger of inconsistent rulings with the FCC) (citing *Ellis v. Tribune Television*, 443 F.3d 71, 82-83 (2d Cir. 2006); *Collins v. Olin*, 418 F. Supp. 2d 34, 45 (D. Conn. 2006) (same, with respect to Connecticut Dept. of Environmental Protection); *S. New England Tel. v. Global Naps*, 2005 WL 2789323, at *6 (D. Conn.) (issues raised by plaintiff "are very much in flux and currently being considered by the FCC."); *Gilson v. Trader Joe's*, 63 F. Supp. 1114, 1117 (N.D. Cal. 2014) ("FDA appears to be actively considering" the issue presented); *Gitson v. Clover Stornetta Farms*, 2014 WL 2638203, at *6 (same); *Ivie v. Kraft Foods Global*, 2013 WL 685372, at *7 (N.D. Cal.) (FDA issued a proposed regulation); *Taradejna v. General Mills*, 909 F. Supp. 2d 1128, 1135 (D. Minn. 2012) (same).

anyone dissatisfied with an organic certification to appeal it to the Secretary, not to a court.

The fourth factor is whether a prior application to the agency has been made. *Ellis*, 443 F.3d at 83. Here, as explained above, USDA is already engaged in formal rulemaking.

Given that all four factors favor deferring to USDA's primary jurisdiction, that is what this Court should do. *See, e.g., Jackson v. Swift-Eckrich*, 836 F. Supp. 1447, 1455-56 (W.D. Ark. 1993) (deferring to USDA); Order, *Parker Livestock v. Oklahoma City Nat'l Stock Yards*, No. 13-cv-518, Dkt. 34, at 8 (W.D. Okla. 2013) (attached hereto as Ex. 22) (same, to promote uniform application of statute). Rather than accept Plaintiffs' invitation to "interpret and apply federal organic standards, potentially create a conflict with those standards, and … intrude upon and undermine the USDA's authority," *All One God Faith v. Hain Celestial Group*, 2012 WL 3257660, at *11 (N.D. Cal.), Plaintiffs' complaint should be stayed or dismissed.

As two examples will show, the need to defer to USDA's primary jurisdiction would remain even if it could somehow be determined that the proposed rule will be enacted without change as a final rule. As explained above, the proposed rule would *allow* in organic infant formula synthetic ingredients to provide nutrients that the Infant Formula Act requires in all infant formulas. As an example, one of those, which Plaintiffs challenge, is sodium selenate. (Compl. ¶¶ 3, 18.) Plaintiffs describe it as a "toxic compound" that is "extremely hazardous in the case of ingestion." (Compl. ¶¶ 3, 18, 27(a).). But the sodium selenate provides selenium, which is ***essential*** to human nutrition—everyone ***must*** ingest it, and it is required by law in all infant formula. (Ex. 23, Infant Formula: The Addition of Minimum and Maximum Levels of Selenium, 80 Fed. Reg. 35,834 (June 23, 2015); Ex. 24, National Institutes of Health, *Selenium*, https://ods.od.nih.gov/factsheets/Selenium-HealthProfessional/ (selenium is "nutritionally essential for humans," often ingested in the form of selenate, and provided to infants in formula).) As explained above, the Infant Formula Act also requires other ingredients (such as biotin) that Plaintiffs challenge. Thus, even if the proposed rule were forthcoming as a final rule, parts of Plaintiffs' complaint are not viable. Only time will tell what the final rule says, and this Court should defer to USDA's primary jurisdiction until the final rule is complete.

As a second example, the Board has, as explained above, ***approved*** for separate addition to the National List five ingredients Plaintiffs challenge. USDA may now by rulemaking add those ingredients to the National List, in which case they may continue to be used in organic infant formula whether or not USDA amends the current "nutrient vitamins and minerals" exception. Again, only time will tell what USDA does, and this Court should invoke the doctrine of primary jurisdiction to allow USDA time to finish the process that is already underway.

D. Plaintiffs' claims have no merit, because federal law today still allows the challenged ingredients in organic infant formula.

If this Court is to rule on whether Plaintiffs have stated a claim, this motion should still be granted, because, as explained above, federal law today continues to allow accessory nutrients in organic infant formula. USDA's interim rule continued the existing "nutrient vitamins and minerals" entry on the National List, until October 2017 or until the final rule is issued, and the final rule is likely to be followed by a two-year implementation period before any new regulation actually goes into effect. And USDA has consistently ruled that this entry allows organic infant formulas, and Similac Organic in particular, to contain all of the challenged ingredients.[14]

It is not sufficient for Plaintiffs to assert, as they do, that USDA or the Board changed its attitude toward accessory nutrients in 2011 or 2012. (Compl. ¶ 37.) A change in attitude or interpretation does not delete an entry from the National List. The National List can only be amended through the use of formal notice-and-comment rulemaking, 7 U.S.C. § 6517(d)(4); *see*

[14] All of the challenged ingredients are accessory nutrients covered by the "nutrient vitamins and minerals" exception. Ex. 7, Technical Evaluation Report, at 2-5 (beta-carotene, cholecalciferol, lutein, ascorbyl palmitate. cyanocobalamin, calcium pantothenate, biotin, choline chloride, choline bitartrate; M-inositol, sodium selenate); Ex. 25, Technical Evaluation Report, Docosahexaenoic Acid (DHA) Algal Oil (Aug. 26, 2011), at 2:67-68 ("DHA is considered an accessory nutrient by the USDA."); Ex. 26, Technical Evaluation Report, Arachidonic Acid Single-Call Oil (ARA) (Aug. 19, 2011), at 2:61 ("ARA is considered an accessory nutrient by" USDA); Ex. 27, Technical Evaluation Report, Nucleotides (Apr. 25, 2012), at 6:189-207 (nucleotides are "nutrient vitamins and minerals"); Ex. 28, Technical Evaluation Report, Taurine (June 25, 2012), at 4:160-178 (same, for taurine); Ex. 29, Technical Evaluation Report, L-Carnitine (June 25, 2012), at 5:211-216 (same, for L-carnitine); Ex. 30, Letter from Barbara O. Schneeman, Ph.D, Director, FDA Office of Nutrition, Labeling, and Dietary Supplements to National Organic Program (Apr. 14, 2011), (available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5090415) (taurine); Ex. 31, S. Rep. 103-410, 1994 WL 562259, at *12-13 (Oct. 8, 1994) (L-carnitine).

generally Perez v. Mortgage Bankers Ass'n, 135 S. Ct. 1199, 1203 (2015), which is how the "nutrient vitamins and minerals" exception was added to the National List in the first place, and which is the process USDA is now using to amend that exception. An exception that has been renewed for another five-year term, as this one was in September 2012 by the interim rule, is valid for another five years. *Id.* § 6517(e).

The decision in *Backus v. General Mills* is on point. There, FDA issued a rule in 2015 determining that oils containing trans fats were no longer GRAS, but FDA postponed the compliance date for three years, until 2018. *Backus*, 2015 WL 4932687, at *18-19. The three-year implementation period was designed to allow the food industry time to petition to have small amounts of oils containing trans fats approved for use, and to reformulate products as necessary. *Id*. at *12. Plaintiff sued, asserting that FDA had banned trans fats and that the defendant's sale of those products in the past violated federal law. *Id*. at *4, 6. The court rejected his claim on the grounds that oils containing trans fats "were widely treated as GRAS" before the FDA's new rule, and FDA had in any event "permitted their continued use until 2018." *Id*. at *12. The situation is the same here, except that USDA has not yet even issued its final rule.

In short, Abbott, like all other makers of organic infant formula, is entitled to add to it ingredients that USDA has explicitly allowed, until USDA actually disallows them. That has not yet happened. It might never happen. Only the final rule will tell. As of today, the ingredients are all approved, so the entire Complaint should be dismissed on its merits.

E. Plaintiffs fail to state any claim because Similac Organic's label is indisputably true and not misleading to a reasonable consumer.

The statements about which Plaintiffs complain—"USDA ORGANIC" and "organic"—are indisputably true and not misleading as a matter of federal law. There can therefore have been no breach of express warranty, no consumer fraud, no false advertising, no violation of the California Organic Products Act, and no unjust enrichment. Plaintiffs' claims all fail.

Under federal law, "USDA ORGANIC" and "organic" simply mean that the maker of a product was certified as organic, as Abbott, maker of Similac Organic, undeniably was. As one

court wrote, when dismissing a lawsuit asserting (as Plaintiffs assert here) that organic infant formula was not in fact organic: reasonable consumers would not "assume [the] … products are any more organic than what organic certifying agencies require." *Gedalia v. Whole Foods*, 2014 WL 5315030, at *9 (S.D. Tex. 2014); *see also Red v. Kroger*, 2010 WL 4262037, at *4 (C.D. Cal.) ("Plaintiffs fail to convincingly reconcile the FDA's specific definitions [of "cholesterol free" and "0% trans fats"] with their contention that the use of such permissible defined terms is false and misleading."); *Manchouck v. Mondelez Int'l*, 2013 WL 5400285, at *3 (N.D. Cal.) (dismissing plaintiff's claims because label statement was true); *Hairston v. S. Beach Beverage*, 2012 WL 1893818, at *5 (C.D. Cal.) (same). All of Plaintiffs' claims should be dismissed.

During the discussion about express warranty at the pre-motion conference, the Court cited *In re Frito Lay*, 2013 WL 4647512 (E.D.N.Y.). That decision arose in a very different regulatory context, involving a label that described the product as "All Natural." *Id*. at *1. As the decision explains, "FDA has not promulgated any formal rule or policy explaining when a food may be labeled 'natural.'" *Id*. at 7. The decision recognized that in the organic realm, by contrast, Congress and USDA have "promulgated regulations on the use of the term 'organic' in food labeling." *Id*. at *14. The decision in *Frito Lay* noted that the plaintiffs there did "not allege, nor do defendants assert, that the products at issues here are 'products sold as organic.'" *Id*. at *23.

Plaintiffs also cannot plead that they plausibly or reasonably relied on the "organic" label statements to indicate the product lacks ingredients that appear on the label. Under California's "reasonable consumer" standard, plaintiffs must show that "members of the public are likely to be deceived." *Williams v. Gerber Prods.*, 552 F.3d 934, 938 (9th Cir. 2008); *Lavie v. Procter & Gamble*, 105 Cal. App. 4th 496, 508 (2003). And under New York law, "[t]here can be no claim for deceptive acts or practices … when the alleged deceptive practice was fully disclosed." *Weinstein v. eBay*, 819 F. Supp. 2d 219, 227-28 (S.D.N.Y. 2011). These objective determinations can be made as a matter of law. *See, e.g., Weinstein*, 819 F. Supp. at 228-29; *Hairston v. S. Beach Beverage*, 2012 WL 1893818, at *4 (C.D. Cal.); *Lavie*, 105 Cal. App. 4th at 508.

Here, Plaintiffs' claims depend on their professed belief that Similac Organic did not

contain the challenged ingredients. Yet Plaintiffs cannot have relied on the USDA ORGANIC logo or the word "organic" for that belief, because all of the ingredients appear on the product label (Compl. ¶ 25; *id.* Ex. 1 at 3, 7, 10, 11 (ingredients).). *See, e.g., Gitson v. Trader Joe's*, 2013 WL 5513711 (N.D. Cal.) (reasonable consumer could not possibly be deceived into believing that organic soy milk was cow's milk, because the label plainly stated the product was "Organic Soy Milk" and "LACTOSE & DAIRY FREE"); *Kane v. Chobani*, 2013 WL 5289253 (N.D. Cal.) (product label disclosed ingredients, so plaintiff could not plausibly believe the product did not contain them); *Hairston*, 2012 WL 1893818, at *5 (even if a product label was ambiguous, "it is clarified by the detailed information contained in the ingredient list, which explains the exact contents" of the product); *see generally Freeman v. Time*, 68 F.3d 285, 289-90 (9th Cir. 1995) (the reasonable consumer inquiry requires considering the entire context of the label).

In fact, three challenged ingredients—DHA, ARA, and lutein—are featured on the *front* of the label. (Compl. Ex. 1 at 1, 2, 6.) Plaintiffs do not allege they were somehow unable to read the list of ingredients on the label. "Plaintiff's selective interpretation of individual words or phrases from a product's labeling cannot support" claims that a label misled consumers. *Hairston*, 2012 WL 1893818, at *4. The entire complaint should therefore be dismissed.

F. Plaintiffs fail to state a claim under New York GBL § 349.

Plaintiffs' claim under New York General Business Law § 349 (count 2) fails for yet another reason. An actionable injury is essential to a section § 349 claim. *Small v. Lorillard Tobacco*, 679 N.Y.S.2d 593, 599 (1998) *aff'd*, 94 N.Y.2d 43 (1999). Section 349(h), which was added to the original statute to give private parties a right of action, grants that right ***only*** to "any person who has been injured" by deceptive business practices. *Id.* Thus, in order to state a claim, a plaintiff seeking damages must show that the defendant engaged in a material deceptive act or practice that caused the plaintiff actual harm. *Id.*

The New York Court of Appeals has, however, specifically *rejected* the argument that "consumers who buy a product that they would not have purchased, absent a manufacturer's deceptive commercial practices, have suffered an injury." *Small v. Lorillard Tobacco*, 94 N.Y.2d

43, 56 (1999). A plaintiff must allege some harm other than being tricked into buying the product. *Id.; Preira v. Bancorp Bank*, 885 F. Supp. 2d 672, 676 (S.D.N.Y. 2012) ("New York courts have rejected the notion that a defendant's deception alone—in other words, allegations of pecuniary loss arising solely from the purchase of the defendant's product—may suffice to plead 'actual injury' for a Section 349 claim."); *Pelman v. McDonald's*, 272 F.R.D. 82, 92-93 (S.D.N.Y. 2010) (pecuniary loss for the wrongful purchase of a product is not an actionable injury); *Rice v. Penguin Putnam*, 734 N.Y.S.2d 98, 99-100 (App. Div. 2001) (being tricked into purchasing a book is not an actionable injury).

Yet that is precisely what Plaintiffs allege here. They allege that had they "known at the time that the 'Organic' Infant Formula they purchased was not organic as promised, they would not have purchased the 'Organic' Infant Formula. (Compl. ¶ 19.) They allege no other injury, such as a personal injury. Thus, they failed to state a claim.

G. Plaintiffs fail to state a claim for breach of express warranty under New York law.

Plaintiff's claim for breach of express warranty under New York law (count 1) fails for the additional reason that the New York Plaintiffs did not provide Abbott with the required pre-suit notice. Under New York law, a buyer "must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." N.Y. U.C.C. § 2-607(3)(a); *see also In re Frito-Lay N. Am. All Natural Litig.*, 2013 WL 4647512, at *27 (E.D.N.Y. 2013) (dismissing claim for breach of express warranty because plaintiffs did not provide notice to defendants prior to commencing the litigation). The New York Plaintiffs fail to allege that they *ever* provided such notice, let alone notice within a reasonable time after their discovery of a breach. Their warranty claim must be dismissed.

CONCLUSION

Abbott respectfully urges the Court to dismiss Plaintiffs' entire complaint with prejudice, or in the alternative to stay the case until USDA's final rule goes into effect, after any implementation period that USDA provides.

APPENDIX A

As shown in this chart, all of the ingredients that Plaintiffs challenge in Similac Organic (Compl. ¶ 27) are found in the other major brands of organic infant formula:[15]

Ingredient	**Similac Advance Organic**	**Nature's One Baby Only Organic**	**Earth's Best Organic**	**Vermont Organics**	**Bright Beginnings**	**Wal-Mart Parent's Choice Organic**	**Whole Foods 365 Everyday Value Organic**
Sodium selenate or selenite	yes	yes	yes	yes	yes	yes	yes
Nucleotides	yes	--	yes	yes	yes	yes	yes
Taurine	yes	yes	yes	yes	yes	yes	yes
DHA	yes	yes	yes	yes	yes	yes	yes
ARA	yes	yes	yes	yes	yes	yes	yes
Ascorbyl palmitate	yes	--	yes	yes	yes	yes	yes
Calcium pantothenate	yes	yes	yes	yes	yes	yes	yes
Choline chloride or bitartrate	yes	yes	yes	yes	yes	yes	yes
Cyanocobalamin	yes	yes	yes	yes	yes	yes	yes
L-carnitine	yes	--	--	yes[16]	--	--	--
Cholecalciferol (vitamin D)	yes	yes	yes	yes	yes	yes	yes
Carotenoids: beta-carotene, lutein, and/or retinyl palmitate	yes	yes	yes	yes	yes	yes	yes
Inositol	yes	yes	yes	yes	yes	yes	yes
Biotin	yes	yes	yes	yes	yes	yes	yes

[15] Ingredient lists for all of these products are publicly available. https://naturesone.zendesk.com/hc/en-us/articles/201457446-Baby-s-Only-Organic-Dairy-with-DHA-Ingredients (Nature's One Baby Only Organic); http://www.earthsbest.com/products/product/ 2392310040 (Earth's Best Organic); http://www.vermontorganicsformula.com/Organic-Baby-Formula.aspx (Vermont Organics, milk formula); http://www.vermontorganicsformula.com/Organic-Soy-Formula.aspx (Vermont Organics, soy formula); http://www.brightbeginnings.com/organic.aspx (Bright Beginnings); http://www.walmart.com/ip/Parent-s-Choice-Organic-Milk-Based-Powder-Formula-with-Iron-23.2oz/16932132 (Wal-Mart Parent's Choice Organic). The ingredients list for Whole Foods 365 Everyday Value Organic is not listed on the Whole Foods website, but can be located on the product container at any Whole Foods store.

[16] Vermont Organics' soy-based organic infant formula contains L-carnitine.

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Respectfully Submitted,

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